

We claim:

1. A device for the controlled release of one or more drugs, comprising:
  - an implantable stent having at least two reservoirs therein, wherein each reservoir defines an opening in the implantable stent;
  - at least two discrete reservoir caps, wherein each discrete reservoir cap covers substantially the entire opening defined by a respective reservoir; and
  - a release system contained in each of the at least two reservoirs, wherein the release system comprises one or more drugs for release at a controlled rate.
2. The device of claim 1, wherein the discrete reservoir caps are disintegrable in vivo to control the time of release of the one or more drugs from the at least two reservoirs.
3. The device of claim 1, wherein the reservoir cap has a thickness between 0.1 and 100 microns.
4. The device of claim 1, wherein the at least one or more drugs comprises a chemotherapeutic agent.
5. The device of claim 1, wherein the release system comprises one or more drugs in a biodegradable or water-soluble matrix.
6. The device of claim 5, wherein at least one of the drugs is heterogeneously distributed in the matrix.
7. The device of claim 5, wherein at least one of the drugs is homogeneously distributed in the matrix.
8. The device of any one of claims 5-7, wherein the matrix comprises one or more synthetic polymers.

9. The device of claim 1, wherein the release system of at least one of the reservoirs comprises two or more biodegradable or water-soluble layers.

10. The device of claim 1, wherein the amount of one drug provided for release from at least a first of the reservoirs is different from the amount of the drug provided for release from at least a second of the reservoirs.

11. The device of claim 1, wherein the time of release of one of the drugs from at least a first of the reservoirs is different from the time of release of the drug from at least a second of the reservoirs.

12. The device of claim 1, wherein a first drug is in at least one of the reservoirs and a second drug is in at least one other of the reservoirs, the first drug and the second drug being different in kind or dose.

13. The device of claim 1, wherein each of the at least two reservoirs comprises at least two layers of a release system and at least one layer of a degradable or dissolvable material which does not comprise the one or more drugs.

14. The device of claim 9, wherein at least a first drug is contained in a first layer of the two or more layers, and wherein a second drug is contained in a second layer of the two or more layers.

15. The device of claim 1, wherein the release system provides release of the one or more drugs towards tissue surrounding the implanted stent.

16. The device of claim 1, wherein the release system provides release of the one or more drugs into a biological fluid passing through the implanted stent.

17. The device of claim 1, which provides pulsatile release of the one or more drugs.

18. The device of claim 1, wherein the implantable stent is formed of a metal.

19. The device of claim 1, wherein at least one of the discrete reservoir caps comprises a polymeric material.

20. The device of claim 1, wherein at least one discrete reservoir cap is formed of a first material and at least one other discrete reservoir cap is formed of a second material, wherein the first material has a different degradation rate, a different dissolution rate, or a different permeability to the drug molecules compared to the second material.

21. The device of claim 1, wherein at least one discrete reservoir cap has a first thickness and at least one other discrete reservoir cap has a second thickness, wherein the first thickness is different from the second thickness, thereby providing different times of release of the one or more drugs from the reservoirs covered respectively by the discrete reservoir cap having the first thickness and the discrete reservoir cap having the second thickness.

22. The device of claim 1, comprising at least two rows of said at least two reservoirs in an array in the implantable stent.

23. The device of claim 22, wherein a first release system is in each of the at least two reservoirs of a first row and a second release system is in each of the at least two reservoirs of the other of the at least two rows other of the reservoirs, the first release system releasing the one or more drugs at a rate or in a dosage amount different from release of the one or more drugs from the second release system.

24. The device of claim 1, wherein each discrete reservoir cap covers the entire opening defined by a respective reservoir.

25. A device for the controlled release of one or more drugs, comprising:
- an implantable non-degradable stent;
  - at least two reservoirs in the stent, wherein each of the at least two reservoirs are covered by a discrete reservoir cap; and
  - a release system contained in each of the at least two reservoirs, wherein the release system comprises one or more drugs for release at a controlled rate,
- wherein each discrete reservoir cap are disintegrable in vivo to control the time of release of the one or more drugs.
26. The device of claim 25, wherein each reservoir cap has a thickness between 0.1 and 100 microns.
27. The device of claim 25, wherein the at least one or more drugs comprises a chemotherapeutic agent.
28. The device of claim 25, wherein the release system comprises one or more drugs in a biodegradable or water-soluble matrix.
29. The device of claim 28, wherein at least one of the drugs is heterogeneously distributed in the matrix.
30. The device of claim 28, wherein at least one of the drugs is homogeneously distributed in the matrix.
31. The device of any one of claims 28-30, wherein the matrix comprises one or more synthetic polymers.
32. The device of claim 25, wherein the release system of at least one of the reservoirs comprises two or more biodegradable or water-soluble layers.

33. The device of claim 25, wherein the amount of one drug provided for release from at least a first of the reservoirs is different from the amount of the drug provided for release from at least a second of the reservoirs.

34. The device of claim 25, wherein the time of release of one of the drugs from at least a first of the reservoirs is different from the time of release of the drug from at least a second of the reservoirs.

35. The device of claim 25, wherein a first drug is in at least one of the reservoirs and a second drug is in at least one other of the reservoirs, the first drug and the second drug being different in kind or dose.

36. The device of claim 25, wherein each of the at least two reservoirs comprises at least two layers of a release system and at least one layer of a degradable or dissolvable material which does not comprise the one or more drugs.

37. The device of claim 32, wherein at least a first drug is contained in a first layer of the two or more layers, and wherein a second drug is contained in a second layer of the two or more layers.

38. The device of claim 25, wherein the release system provides release of the one or more drugs towards tissue surrounding the implanted stent.

39. The device of claim 25, wherein the release system provides release of the one or more drugs towards a biological fluid passing through the implanted stent.

40. The device of claim 25, which provides pulsatile release of the one or more drugs.

41. The device of claim 25, wherein the non-degradable stent is formed of a metal.

42. The device of claim 25, wherein at least one of the discrete reservoir caps comprises a polymeric material.

43. The device of claim 25, wherein at least one discrete reservoir cap is formed of a first material and at least one other discrete reservoir cap is formed of a second material, wherein the first material has a different degradation rate, a different dissolution rate, or a different permeability to the drug molecules compared to the second material.

44. The device of claim 25, wherein at least one discrete reservoir cap has a first thickness and at least one other discrete reservoir cap has a second thickness, wherein the first thickness is different from the second thickness, thereby providing different times of release of the one or more drugs from the reservoirs covered respectively by the discrete reservoir cap having the first thickness and the discrete reservoir cap having the second thickness.

45. The device of claim 25, wherein each reservoir defines an opening in the implantable stent and each discrete reservoir cap covers the entire opening defined by a respective reservoir.

46. The device of claim 25, comprising at least two rows of said at least two reservoirs in an array in the implantable stent.

47. The device of claim 46, wherein a first release system is in each of the at least two reservoirs of a first row and a second release system is in each of the at least two reservoirs of the other of the at least two rows other of the reservoirs, the first release system releasing the one or more drugs at a rate or in a dosage amount different from release of the one or more drugs from the second release system.

48. A device for the controlled release of one or more drugs, comprising:  
an implantable metallic stent;  
at least two reservoirs in the stent; and  
a release system, contained in each of the at least two reservoirs, the release system comprising two or more layers of a biodegradable or water-soluble matrix material and a therapeutic agent distributed therein;  
wherein the matrix material degrades or dissolves in vivo to controllably release the therapeutic agent.

49. The device of claim 48, wherein the therapeutic agent comprises a chemotherapeutic agent.

50. The device of claim 48, wherein the therapeutic agent is heterogeneously distributed in the release system.

51. The device of claim 48, wherein the matrix material comprises one or more synthetic polymers.

52. The device of claim 48, wherein the amount of the therapeutic agent provided for release from at least a first of the reservoirs is different from the amount of the therapeutic agent provided for release from at least a second of the reservoirs.

53. The device of claim 48, wherein the time of release of the therapeutic agent from at least a first of the reservoirs is different from the time of release of the therapeutic agent from at least a second of the reservoirs.

54. The device of claim 48, wherein the therapeutic agent is in at least one of the reservoirs and a second therapeutic agent is in at least one other of the reservoirs, the first therapeutic agent and the second therapeutic agent being different in kind or dose.

55. The device of claim 48, wherein the release system of at least one reservoir further comprises at least one layer of a degradable or dissolvable material which does not comprise the therapeutic agent.

56. The device of claim 48, wherein the release system provides release of the therapeutic agent towards tissue surrounding the implanted stent.

57. The device of claim 48, wherein the release system provides release of the therapeutic agent towards a biological fluid passing through the implanted stent.

58. The device of claim 48, which provides pulsatile release of the therapeutic agent.

59. The device of claim 48, wherein each of the at least two reservoirs comprise a discrete reservoir cap which covers the release system contained therein.

60. The device of claim 59, wherein each discrete reservoir caps comprises a polymeric material, the in vivo disintegration of which controls the time at which release of the therapeutic agent is initiated.

61. The device of claim 59, wherein at least one discrete reservoir cap is formed of a first material and at least one other discrete reservoir cap is formed of a second material, wherein the first material has a different degradation rate, a different dissolution rate, or a different permeability to the drug molecules compared to the second material.



62. The device of claim 59, wherein at least one discrete reservoir cap has a first thickness and at least one other discrete reservoir cap has a second thickness, wherein the first thickness is different from the second thickness, thereby providing different times of release of the one or more drugs from the reservoirs covered respectively by the discrete reservoir cap having the first thickness and the discrete reservoir cap having the second thickness.

63. The device of claim 59, wherein each reservoir defines an opening in the implantable stent and each discrete reservoir cap covers the entire opening defined by a respective reservoir.

64. The device of claim 48, comprising at least two rows of said at least two reservoirs in an array in the implantable stent.

65. The device of claim 64, wherein a first release system is in each of the at least two reservoirs of a first row and a second release system is in each of the at least two reservoirs of the other of the at least two rows other of the reservoirs, the first release system releasing the one or more drugs at a rate or in a dosage amount different from release of the one or more drugs from the second release system.

66. A method for delivering a therapeutic agent into a patient comprising:

implanting a metallic stent at a site in a patient, the stent comprising a plurality of reservoirs containing a release system, wherein the release system comprising two or more layers of a biodegradable or water-soluble matrix material and a therapeutic agent distributed therein; and

contacting the matrix with one or more biological tissues or fluids in vivo to cause the matrix to degrade or dissolve, thereby releasing the therapeutic agent into the patient at a controlled rate.

67. A method for delivering a therapeutic agent into a patient comprising:

implanting a metallic stent at a site in a patient, the stent comprising at least two reservoirs in the stent wherein each of the at least two reservoirs are covered by a discrete reservoir cap, a release system contained in each of the at least two reservoirs, the release system comprising a therapeutic agent, wherein each discrete reservoir cap is disintegrable in vivo to control the time of release of the therapeutic agent;

contacting the reservoir caps with one or more biological tissues or fluids in vivo to cause the reservoir cap to degrade or dissolve; and then

contacting the release system with the one or more biological tissues or fluids in vivo to cause the therapeutic agent to be released at a controlled rate into the patient.

68. The method of claim 66 or 67, wherein the therapeutic agent comprises a chemotherapeutic agent.

69. The method of claim 66 or 67, wherein the therapeutic agent is heterogeneously distributed in the release system.

70. The method of claim 66 or 67, wherein the release system comprises one or more synthetic polymers, which are biodegradable or water soluble.

71. The method of claim 66 or 67, wherein the therapeutic agent comprises an anti-restenosis drug and is locally delivered to the site which comprises an artery.

72. The method of claim 66 or 67, wherein the therapeutic agent is released from the device to the site over a period of time of at least three months.